DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 22, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 99-15

Ted Mobley, Owner & General Manager
Alaska Live Crab Company
P.O. Box 19534
Seattle, Washington 98109

WARNING LETTER

Dear Mr. Mobley:

On February 18, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm, Alaska Live Crab Company, 4041 W. International Airport Road, Anchorage, Alaska. At the conclusion of the inspection, Daniel J. Starkey, Plant Manager, was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the cooked crab processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Your firm did not have sanitation monitoring records to document the monitoring of the eight points of sanitation. 21 CFR Part 123.11(c) requires you to maintain records of sanitation monitoring and any corrections made as a result of that monitoring. During the March 1998 inspection, and in a letter from the FDA, dated May 15, 1998, you were notified of the requirement to maintain sanitation monitoring records. The FDA is concerned that in 11 months' time, your firm did not correct this deficiency.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

2. Your firm was not maintaining calibration records for the thermometer used to monitor the cook step critical control point. 21 CFR Part 123.8(d) requires you to keep records of any calibration performed on equipment used to monitor critical control points.

3. Four (4) processing records generated between January 27, 1999, through February 6, 1999, were not reviewed within one week, as required under 21 CFR Part 123.8(a)(3)(i).

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Roger L. Lowell
District Director

3 Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement